



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,597	10/12/2004	Joseph P. Errico	SPINE 3.0-437 CIPCIPCIPCI	8309
51640 SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090	7550 03/16/2011		EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 03/16/2011	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,597

Applicant(s)

ERRICO ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 15-18 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 15-18 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/25/10
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The Examiner acknowledges receipt of the lengthy information disclosure statement filed October 25, 2010 citing 326 references. In the three (3) information disclosure statements filed to date, a total of 396 references and documents have been cited. There is no requirement that applicants explain the materiality of English language references, however the cloaking of a clearly relevant reference in a long list of references may not comply with applicants' duty to disclose; see Penn Yan Boats, Inc. v. Sea Lark Boats, Inc., 359 F. Supp. 948, aff'd 479 F. 2d. 1338. There is no duty for the Examiner to consider these references to a greater extent than those ordinarily looked at during a regular search by the Examiner. Accordingly, the Examiner has considered these references in the same manner as references encountered during a normal search of Office search files.

Response to Arguments

Applicant's arguments filed 1/7/11 have been fully considered but they are not persuasive. Applicants argue that Paponneau does not disclose a "solid structure comprising a trunk and baseplates". However, this is not what is claimed. According to the claims, the structure as required by the claims can be a plurality of elements forming a "unitary structure" because in giving the ordinary definition of the term "unitary" which is defined by WordNet as: of or pertaining to or involving the use of units. Thus, multiple

elements can make up a "unit" just as in the military a plurality of soldiers form a "unit". In the claim, the device is considered to also require the elements as recited in the claim to form a "solid structure" which is interpreted only to mean that it is rigid in a physical state and not something that is flexible or pliable.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Clearly, the teaching of Boriani as combined with Paponneau is clearly an obvious expedient as using the teachings of Boriani does nothing to destroy the function of Paponneau's structure, but only modifies a perimeter such that the tool can engage such a surface. Paponneau is silent as to a tool, but it is well known in the orthopedic art that surgeons use such tools as taught by Boriani to deliver and accurately place these spinal implants. Thus, such an argument is unpersuasive.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-7,10,11,13,18,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (2003/176925) in view of Boriani et al. (6159211). The examiner is interpreting the claimed elements "integrally coupled" in this way: elements that are *formed as a unit with other parts* as defined by Merriam-Webster Online Dictionary. Additionally, the term "unitary" as defined by **WordNet** as: of or pertaining to or involving the use of units. Thus, multiple pieces can form a "unitary structure. In interpreting forming a "unitary, solid structure" this can mean just that the structure formed is rigid and not flexible. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Paponneau discloses (Fig. 1) apparatus for preparing an intervertebral space with two baseplates **24, 26** and can be considered integrally coupled via cylindrical trunk **22**. Fig. 2 shows clips to "integrally couple" the plates together. Since the plates will not separate once connected to the trunk via the snap connections the baseplates are "integrally coupled" to the trunk. Fig. 3 shows the baseplates include a plurality of engagement holes **64A-C, 66A-C** extending into the baseplate to a direction substantially perpendicular to the plurality of surgical approach directions. Regarding claim 4, Fig. 8A illustrates the plates can be angled with respect to one another and can be approximately 15 degrees. Regarding claims 6,7, since there is space about the trunk because it is smaller in width than the plates it forms a "groove" and is thus annular. With respect to claims 10,11, the apparatus is fully capable of being used in any of the surgical approach directions, such as an anterior or anterior-lateral approach. Regarding claim 20 since the baseplates

have a thickness, it can be said that there is a surface facing an anterior surgical approach direction and two anterior-laterally facing surfaces extending perpendicular to the anterior-lateral approach. However, Paponneau does not disclose the plates having an anterior facing surface extending perpendicular to the anterior surgical approach and two anterior-laterally facing surfaces each extending at an angle from the anteriorly facing surface. Boriani et al. teach (Fig. 19) a plate having an anterior facing surface **88** extending perpendicular to the anterior surgical approach and two anterior-laterally facing surfaces each extending at an angle from the anteriorly facing surface. Each of the faces has engagement structure for one of the surgical approach directions, col. 4, lines 27-31 of Boriani. It would have been obvious to one of ordinary skill in the art to modify the surface of the baseplates of Paponneau and incorporate an anterior facing surface extending perpendicular to the anterior surgical approach and two anterior-laterally facing surfaces each extending at an angle from the anteriorly facing surface as taught by Boriani et al. such that it gives the surgeon the ability to orient the structure from different angles giving greater versatility. With respect to claim 13 Boriani can be said have an anterior facing surface angled at "approximately 33.4 degrees" with respect to each of the anterior-laterally facing surfaces.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (2003/176925) in view of Boriani et al. '211 as applied to claim 1 above, and further in view of Kuras (6607558). Paponneau in view of Boriani et al. is explained supra. However, Paponneau as modified with Boriani fail to disclose the contour of the outward facing surface of the baseplates to have a contour of a dome. Kuras teaches

(Figs. 1-3) a spinal device that has two upper and lower support structures **20, 40** with convex or domed outward facing surfaces **22, 42** for engaging the disc space. It would have been obvious to one of ordinary skill in the art to use a convex or domed contour as taught by Kuras for the baseplates of Paponneau as modified with Boriani et al. such that it more closely matches the contour of the vertebrae surface that the apparatus is to engage.

Claims 8, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (2003/176925) in view of Boriani et al. '211 as applied to claim 6 above, and further in view of Baumgartner (5370697). Paponneau in view of Boriani et al. is explained supra. However, Paponneau as modified with Boriani fail to disclose the floor of the groove is narrower than an opening of the groove or the groove floor being ridged. Baumgartner teaches (Fig. 1a) a spinal device that has two upper and lower support structures **2, 3** with an inner "groove" having a floor with ridge **21** for holding the trunk component **5**. Baumgartner additionally teaches (col. 2, line 58) a narrower profile for the floor of the "groove". It would have been obvious to one of ordinary skill in the art to modify the baseplates and use a ridged floor as taught by Baumgartner in the baseplates of Paponneau as modified with Boriani such that it more effectively retains the trunk between the two baseplates.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paponneau (2003/176925) in view of Boriani et al. '211 as applied to claim 1 above, and further in view of Nishijima et al. (5899941). Paponneau in view of Boriani et al. is explained supra. However, Paponneau as modified with Boriani fail to disclose the

apparatus baseplates having a combination of different width and depth dimensions. Nishijima et al. teach (Figs. 3a,3b) apparatus for a spinal disc space with the upper and lower baseplates **2, 3** with different width and depth dimensions. Nishijima also teaches that one of the baseplates is to have the central structure integral with the plate, col. 1, lines 51-53. It would have been obvious to one of ordinary skill in the art to simplify the apparatus for the spinal space by making an integral trunk with the baseplate as taught by Nishijima et al. for the apparatus of Paponneau as modified with Boriani et al. such that it reduces the cost of manufacturing by lowering the number of components that would have to be molded. With respect to claims 16,17 Paponneau does not explicitly disclose the width dimension in a range up to 40mm. Boriani et al. teach that the width of the implant body is 40mm, col. 5, lines 17-19. It would have been obvious to one of ordinary skill in the art to use a width of 40mm for the plates as taught by Boriani et al. in the baseplate of Paponneau such that the baseplates have a sufficient dimension to accommodate a lumbar region as taught by Boriani. Regarding claim 17 it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a depth having a range between 14-18mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738